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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,143	05/06/2004	Jayant Ekanth Khanolkar	9626	7415

27752 7590 06/07/2007

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EXAMINER	
EBERHARD, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1609	
MAIL DATE	**DELIVERY MODE**
06/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/840,143	KHANOLKAR ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Eberhard, Ph.D.	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 - 17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Abstract Objected to – Minor Informalities

1. The abstract of the disclosure is objected to because it does not allow the public to quickly determine the nature and gist of the technical disclosure nor include that which is new, and at 36 words, it does not meet the requirements (50-150 words) set forth at 37 CFR 1.72(b). Correction is required. See MPEP § 608.01(b).

Priority

2. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 10/840,143 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be timely made in this application. To satisfy the requirement of 37 CFR 1.55(a)(2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 10/840,143, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The claim reads "a method of improving the stability of a soft gelatin capsule..." A number of (presumably) stable embodiments are taught in the application and it's associated literature citations, but "improved" or "enhanced" is not specifically defined in this context, and a means for assessing said improvement is lacking. Therefore, the claim is rejected for failure to establish criteria for assessing improvement in stability of one particular embodiment over another.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 – 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanner *et al.* (5,569,466).

Tanner *et al.* (at paragraph 20) teach a "dosage unit form comprising a biologically active agent dissolved or suspended in a carrier liquid encapsulated in a soft elastic capsule, wherein the carrier liquid comprises at least about 20% maltitol syrup.

The "dosage unit form comprising a biologically active agent...encapsulated in a soft elastic capsule" taught in Tanner *et al.* is equivalent to the instantly claimed "pharmaceutical

composition comprising...a suspended pharmaceutical active...encapsulated in a soft gelatin capsule." Those of ordinary skill in the art would have recognized the inherent solvent properties of maltitol. Tanner *et al.*'s 20% maltitol anticipates the range for solvents (9% - 39%) specified in the instant claim. The "suspended stabilizing agent" of the instant claim is considered to be within the scope of Tanner *et al.* on the basis of Tanner *et al.*'s claim of excipients. Likewise, other limitations set forth in the instant claims addressing types or classes of pharmaceuticals are within the scope of Tanner *et al.* on the basis of its claim of "pharmaceuticals." Thus, the claims are anticipated by Tanner *et al.*

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 11 - 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, which might be considered enabling for the examples disclosed therein, does not reasonably provide enablement for the breadth of the claims as recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures made in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather is a

conclusion reached by weighing many factors. These factors were outlined in *Ex Parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986, and again in *In Re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and include nature and scope of the invention, state of the art and level of artisan's skill, guidance and examples provided by the applicant, level of predictability, and amount of experimentation.

The nature of the invention is the formulation and use of a dosage form comprising a pharmaceutical active(s), stabilizing agent and solvent(s). Said dosage form is claimed to have enhanced stability by virtue of the addition of the stabilizing agent. The invention requires that one of skill be able to make such a dosage form without empirical, undue and unpredictable trial and error experimentation; *i.e.*, the skilled artisan must be able to recognize what structural features of the individual molecules comprising the ingredients in the dosage form will be compatible with one another such that the skilled artisan can take those structural features, identify other sets of compatible molecules, and create another useful finished (stable) dosage form. It is noted that the ability to "identify" sets of compatible molecules is not equivalent to "make and use" based on the principle above.

The scope of the invention is very broad, encompassing every member of any of the classes of substances recited in the claims and specification of the instant application. However, there are only a few imprecisely described embodiments noted in the application, none of which identify stability conferring features of the various components. Accordingly, the skilled artisan cannot make the broad scope of the invention as claimed.

The state of the art in pharmaceutical dosage formulation is well developed in terms of breadth of knowledge, and in terms of methods for assessing stability of finished dosage

formulations. While there is an element of codified science to the art, the "breadth of knowledge" is actually a very large set of examples that have been well characterized by highly developed analytical techniques. Structural features of the molecules comprising the finished dosage form notwithstanding, environmental factors, variable impurity profiles and the passage of time make dosage form stability prediction impossible without empirical data, and no artisan (skilled or otherwise) is expert in every type of compound or analytical technique.

Thus, the instant specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to employ the invention in a manner that is commensurate in scope with these claims (see MPEP § 2164.08). Accordingly, it would not be possible, even for one skilled in the art, to make and use the invention as claimed.

Application Status and Examiner Contact Information

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Eberhard, Ph.D. whose telephone number is (571) 270-3289. The examiner can normally be reached from 7:30 am to 5:00 pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey S. Eberhard, Ph.D.
Patent Examiner
Art Unit 1609

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JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER